

IN THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Claim 1 (Currently Amended): An implantable device for controlling the internal circumference of an anatomic orifice or lumen, comprising:

an implantable device with a body and having an adjustable member configured to adjust the dimensions of the implantable device over a variable range of functional dimensions, the implantable device configured to ~~accept~~ be coupled to a fastener that provides fastening of said implantable device to tissue around the anatomic orifice or lumen, the implantable device having a surface that comes in direct contact with the anatomic orifice or lumen, said surface substantially defining a plane;

an adjustment tool configured to actuate the adjustable member and provide for adjustment before, during and ~~or~~ after the anatomic orifice or lumen resumes near normal to normal physiologic function; and

wherein when the adjustment tool is coupled to an interface location of the adjustable member, the adjustment tool is positioned in an off-plane, non-planar orientation relative to the plane defined by said surface of the implantable device wherein ~~to provide that~~ the implantable device is adapted to ~~can~~ be adjusted on a beating heart to cause leaflet coaptation and positioned to enable attachment to and adjustment of the implantable device, and detachment from the implantable device and removal from the body under normal physiologic conditions.

Claim 2 (Previously Presented): The implantable device of claim 1, further comprising:

a fastening member that includes a plurality of barbs extending from said implantable device for engaging the tissue around said anatomic orifice or lumen.

Claim 3 (Previously Presented): The implantable device of claim 2, wherein each of the barbs is oriented in a direction with respect to the implantable device to provide that rotational motion of the implantable device in a first direction engages said retention barbs with the desired tissue,

and rotational motion of the implantable device in a direction opposite to said first direction disengages said retention barbs from said desired tissue.

Claim 4 (Previously Presented): The implantable device of claim 3, wherein each of said barbs further includes a hook at its free end.

Claim 5 (Currently Amended): The implantable device of claim 1, wherein said surface fastener device includes an outer fabric sheath covering said implantable device through which sutures can be placed to suture said implantable device to said tissue around said anatomic orifice or lumen.

Claim 6 (Currently Amended): The implantable device of claim 1, further comprising a ~~wherein said fastener~~ device and includes a plurality of grommets spaced around the periphery of said implantable device.

Claim 7 (Currently Amended): The implantable device of claim 6, wherein said one or more sutures anchor said implantable device to the tissue around said anatomic orifice or lumen.

Claim 8 (Currently Amended): The implantable device of claim 6, wherein said grommets are made of a material which is sufficiently configured so ~~soft~~ that a suture can be placed through or around said grommet and through the underlying tissue to anchor said implantable device to the tissue around said anatomic orifice or lumen.

Claim 9 (Previously Presented): The implantable device of claim 6, wherein said grommets include tabs comprised of a material which is sufficiently soft that a suture can be placed through said tab and through the underlying tissue to anchor said implantable device to the tissue around said anatomic orifice or lumen.

Claim 10 (Previously Presented): The implantable device of claim 6, wherein said grommets include tabs that define holes through which a suture can be placed and then through the

underlying tissue to anchor said implantable device to the tissue around said anatomic orifice or lumen.

Claim 11 (Previously Presented): The implantable device of claim 1, wherein the adjustment member includes corrugations.

Claim 12 (Previously Presented): The implantable device of claim 6, wherein said implantable device includes alternating sections of corrugations and grommets spaced around the periphery of said implantable device.

Claim 13 (Previously Presented): The implantable device of claim 1, wherein said implantable device includes a hollow tube formed into an annular shape, said tube having interspaced smooth and corrugated sections disposed around its circumference, wherein said means by which said implantable device can be fastened to the tissue around an anatomic orifice or lumen comprises said tube being sufficiently soft such that a suture can be passed through said tube and hence through the underlying tissue; wherein said means associated with said implantable device for permitting adjustment of the circumference of said implantable device from a first circumference to a second circumference comprises said corrugated sections; and wherein said means associated with said implantable device for maintaining said implantable device in said first circumference and, upon said implantable device being adjusted to said second circumference, for maintaining said implantable device in said second circumference comprises said corrugated sections being sufficiently stiff that once said implantable device is placed in a given configuration, it will tend to remain in said given configuration when acted upon by normal anatomic forces at said selected anatomic orifice or lumen.

Claim 14 (Previously Presented): The implantable device of claim 1, wherein said implantable device includes a hollow tube formed into an annular shape, said tube having interspaced smooth and corrugated sections disposed around its circumference.

Claim 15 (Previously Presented): The implantable device of claim 1, wherein said adjustment

member includes teeth engaged with a gear.

Claim 16 (Previously Presented): The implantable device of claim 15, further comprising:
a wheel positioned tangentially to said gear such that said portion of said implantable device which engages said gear passes between said gear and said wheel.

Claim 17 (Previously Presented): The implantable device of claim 15, wherein said gear is mounted in fixed relation to said second end of said implantable device, and wherein said teeth are formed adjacent said first end of said implantable device.

Claim 18 (Previously Presented): The implantable device of claim 15, wherein said adjustment tool includes

a turning device for turning said gear from a location remote from said gear to provide that a circumference of said implant can be adjusted after closure of surgical incisions and resumption of physiological flow through said orifice or lumen.

Claim 19 (Previously Presented): The implantable device of claim 18, wherein said turning device is disengageable from said gear after completion of adjustments.

Claim 20 (Previously Presented): The implantable device of claim 1, wherein said adjustment member includes a worm gear, and an engagement device coupled with a first end of said implantable device for engaging said worm gear such that rotation of said worm gear effects relative movement between said first end of said implantable device and a second end of said implantable device to adjust a circumference of said implantable device from a first circumference to a second circumference.

Claim 21 (Previously Presented): The implantable device of claim 20, wherein said worm gear has a first angled gear head at its driven end, and includes a shaft in offset relation to said worm gear and having a second angled gear head at a first end thereof, said first and second angled gear heads drivably engaging such that rotation of said shaft drives said worm gear.

Claim 22 (Previously Presented): The implantable device of claim 21 wherein adjustment tool includes a tuning device for turning said shaft from a location remote from said worm gear, and provide for an adjustment of said circumference of said implantable device after closure of surgical incisions and resumption of physiological flow through said orifice or lumen.

Claim 23 (Currently Amended): The implantable device of claim 22, wherein said shaft and said tuning **device** are disengageable from said worm gear after completion of adjustments.

Claim 24 (Previously Presented): The implantable device of claim 1, wherein the fastener is integrated with the implantable device.

Claim 25 (New): The implantable device of claim 1, wherein the adjustable member is configured to adjust at least the circumference of the implantable device.

Claim 26 (New): The implantable device of claim 1, wherein the implantable device is configured to adjust at least the shape of the implantable device.